Building sustainable vaccine industrial capabilities: the industry perspective

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Agenda

- Main challenges to be addressed to improve and increase production capacity
  - DCVMN members
- Avenues for developing countries to address public health needs in the vaccine industry

DECVMN MEMBERS

- TOTAL – 26 MEMBERS
- 8 FULL MEMBERS
- 8 PROSPECTIVE FULL MEMBERS
- 10 ASSOCIATE MEMBERS
- 2 POTENTETIAL NEW MEMBERS
- 10 RESOURCE MEMBERS

DCVMN FULL MEMBERS

- Bharat Biotech, india
- Biological Evans, India
- Bio-Manguinhos/Fiocruz (Brasil)
- CGIB, Cuba
- LG Life Sciences, Korea
- Panacea Biotech Ld, India
- PT BioFarma, Indonesia
- Serum Institute of India

Prospective Full Members

- Institute Finlay, Cuba
- Indian Imunologicals, India
- Instituto Butantan, Brasil
- The BioVac, South Africa
- The Government Pharmaceutical Organization, Thailand
- Laboratorios de Biologicos y Reactivos (Birmex), Mexico
- Cantacuzino Natl Inst Research & Devel Microbiol & Immunol, Romania
- Natl Administr Laborat & Inst of Health ANALIS Dr. Carlos G. Malbran, Argentina

DCVMN Associate members

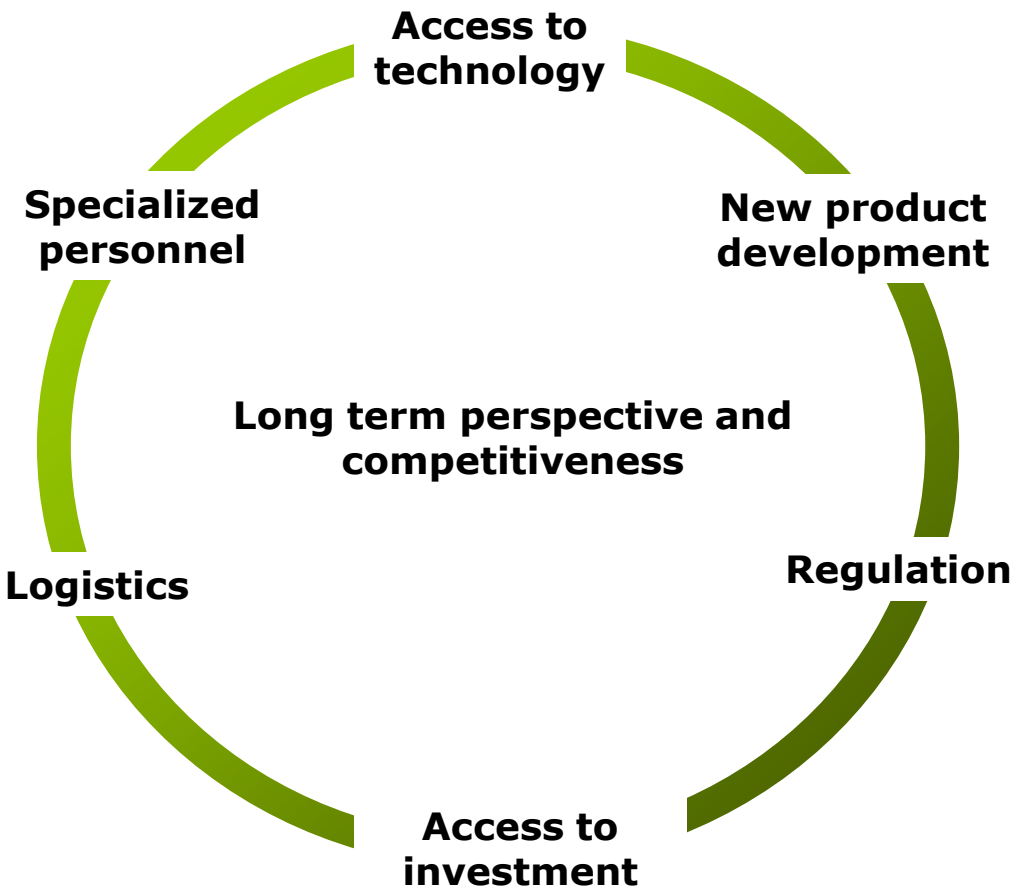
- Bionet Asia Co Ltd, Thailand
- Sinopharm, China
- Inst Vaccines & Medical Biologicals, Vietnam
- Queen Saovabha Memorial Inst, Thailand
- Razi Vaccine & Serum Res Inst, Iran
- VacSera, Egypt
- The Company for Vaccine & Biological No.1, Vietnam
- Xiamen Innovax Biotech Co. Ltd, China
- Sinovac Biotec Ltd, China
- Zhejiang Tianyuan BioPharmaceutical Co. Ltd, China

DCVMN Resource Members

- International Vaccine Institute, Korea
- The Netherlands Vaccine Institute, Netherland
- PATH, USA
- USAID, USA
- Albert B. Sabin Vaccine Institute, USA
- WHO
- UNICEF

Main Challenges ....

- Mission: To provide quality vaccine at affordable prices to the developing countries



Access to technology

- New vaccine technology – Concentration of technology generation in developed countries -monopoly
- Vaccine technology and innovation require high investment, long period of maturation, specialized personnel and facilities, GLP, GMP, GCP, and bear uncertainty of results
- Intellectual Property issues – limits access to new technology

New product development

- Scientific and Technological barriers
  - Low investment in R&D in developing countries
  - GMP Pilot-plants and scaling up facilities
- R&D investments
  - Long term policy of R&D and innovation
  - Public policy to leverage national innovation capabilities
  - Long term planning and foresight capabilities
- Partnership among DCVMN members
  - Components from different producers

Specialized personnel

- Concentration of knowledge and technology generation in developed countries
- Few sites for specialized training and qualification (manufacturing, innovation & validation)
- Limited capability to attract high qualified personnel
- Human resources are developed mostly to the academic enterprise and not to industry

Logistics

- Many key inputs are imported
- Few specialized engineering firms for vaccine facility – project and building
- Lack of vaccine production equipment industries at national level
- Very few specialized equipment maintenance firms
- Inadequate logistics to supply world markets

Access to investment

- Limited access for funding to increase domestic production capacity --- new production facility is highly costly
- High cost of financial resources
- Lack of fiscal incentive to build new enterprises
- Need sustainable and long term demand so that new production capacity is not an uncertain investment
- Government budget constraints turns national vaccine procurement unstable

Regulation Challenges

- Increasing stringent regulatory requirements → high investments
  - Facility and area classification
  - Validation of equipment and facility
  - Validation of production process, QC, QA
  - Qualified personnel
  - Suppliers qualification
- Pre-qualification
  - Local Regulatory Authority
  - New requirements for facility, equipments and procedures
  - Documentation

Long term perspective

- Policy makers and industry must have a long term perspective – sustainable policy
- Vaccine manufacturing is not a commodity industry
  - Industry must be committed to avoid shortages
  - Shortages are not a short term problem
  - Building global industrial and technological capabilities is crucial
    - To create and increase manufacturing capacity
    - To develop new technologies
    - To bring new vaccines at affordable prices

Summing up

- Creating industrial capabilities is not an easy task. It depends on a very complex and delicate balance

Supply side

- **Access to modern technology**
- **Access to investment**
- **Specialized personnel**
- **Logistics**
- **Regulation and pre-qualification**

Demand side

- **Private and/or public sustainable demand**
- **Awareness**
- **Social welfare network**
- **Capability to introduce underused and new vaccines**

Policy side

- **Commitment to public health**
- **Strategies to overcome technological dependency**
- **Long term perspective**

Avenues for developing countries manufacturers

- Creative institutional arrangements
  - DCVMN – WHO– UNICEF – IFPMA - EVM – BMGF – GAVI - other international organizations
- Technology transfer
- R&D partnerships and technology diffusion
- IP, Technology licensing and Public Health
- Economic incentives to turn investments in new production capacity viable
- South-South collaboration
- Advanced Procurement Commitment

Thank you! Shukryia!

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